Original Contribution

When Using Patient-Reported Outcomes in Clinical Practice, the Measure Matters: A Randomized Controlled Trial

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Abstract

Background: Patient-reported outcome (PRO) measures are increasingly being used in clinical practice to inform individual patient management, but evidence is needed on which PROs are best suited for clinical use.

Methods: This controlled trial randomly assigned patients with breast and prostate cancer undergoing treatment to complete one of three PRO measures: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (QLQ-C30), Supportive Care Needs Survey-Short Form (SCNS-SF34), or six domains from the Patient-Reported Outcomes Measurement Information System (PROMIS). Patients completed the PRO measures before clinic visits, and the results were provided to both the patient and clinician. At treatment completion, patients and clinicians completed brief feedback forms on the intervention's usefulness and value. Exit interviews were conducted with patients (at end of treatment) and clinicians (at end of study). The primary outcome was the proportion of patients in each arm who either strongly agreed or agreed to all feedback form items.

Results: Of 294 eligible patients invited to participate, 224 (76%) enrolled (median age 66 years, 78% white, 72% prostate). Of the 181 patients (81%) who completed at least one feedback form item, participants in the QLQ-C30 study arm were most likely to strongly agree/agree to all items (74%) followed by PROMIS (61%) and SCNS-SF34 (52%; $P = .03$). Of the 116 participants (52%) who completed all feedback form items, the results were similar: 82% for the QLQ-C30, 62% for PROMIS, and 56% for SCNS-SF34 ($P = .05$). Clinicians did not prefer one questionnaire over the others.

Conclusion: These results suggest that, when using PROs in clinical practice for patient management, the measure matters in terms of usefulness to patients.

Introduction

The routine collection of patient-reported outcomes (PROs) can promote patient-centered care.[1-6] PROs include symptoms, health-related quality-of-life (HRQOL), supportive care needs, and other outcomes directly reported by patients about their health.[7-8] Use of PROs in clinical practice improves patient-clinician communication and can affect care and outcomes.[1-4,9-14] Technological developments that enable real-time scoring and reporting facilitate the use of PROs in clinical practice.[6,15-16]

Historically, PROs have played a prominent role as outcome measures in clinical trials and other research studies.[17-19] Many PRO measures have been developed,[20] primarily for clinical research purposes. The increasing use of PROs in patient care raises questions regarding whether PRO measures developed for research are appropriate for clinical practice. When PROs are collected as research outcomes, patients complete questionnaires and the data are reported in aggregate (eg, for each treatment arm); patients and their clinicians generally do not see individual patient results. When PROs are collected in clinical care, an individual patient's data are provided to his or her clinician (and frequently the patient) and considered along with other clinical data (laboratory values, imaging reports) to inform that patient's care. Given the differences between the use of PROs for research versus practice, it is not clear whether the same measures are appropriate for both applications.

We previously conducted both qualitative and quantitative studies investigating patient and clinician perspectives on the relevance of common PRO questionnaires for use in clinical practice.[21-22] Building on these preliminary studies, we conducted a randomized controlled trial (RCT) to evaluate three different PRO measures to determine whether one was preferred over the others. The null hypothesis was that there would be no difference between PROs.

Methods

Research Design

In this RCT, patients with breast and prostate cancer at the Johns Hopkins cancer center were randomly assigned 1:1:1 to complete one of three PRO measures. The overall study was conducted in two phases. Phase 1 included radiation oncology patients and clinicians and involved in-person completion of the assigned PRO in the clinic waiting room. In phase 2, the study expanded to medical oncology patients and clinicians, and patients completed their assigned PRO via the Internet before clinic visits.

Participants

Patients with breast and prostate cancer who were being treated by a participating clinician, were age $\geq$ 21 years, and were able

to complete the study questionnaires were eligible. Radiation oncology patients were required to be new patients undergoing external beam radiation therapy expected to last ≥ 3 weeks; medical oncology patients were required to have three or more oncologist visits planned in the next 3 months. Oncology providers or clinic staff gave potentially eligible subjects a flyer describing the study and/or referred them to the study coordinator.

Clinician subjects were eligible if they were a medical oncologist, radiation oncologist, or oncology nurse practitioner with substantial involvement in the treatment of breast or prostate cancer. Clinician participants were recruited via e-mails from the study team. The Johns Hopkins School of Medicine Institutional Review Board approved the study, and both clinician and patient subjects provided written informed consent.

Interventions

At enrollment, patients were randomly assigned to complete one of three PROs based on a list created using a random number generator. The randomization sequence was not concealed, and there was no blinding.

The European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire-Core 30 (QLQ-C30) is a 30-item cancer HRQOL measure that includes five function scales (physical, role, emotional, social, cognitive), eight symptoms (fatigue, pain, nausea and vomiting, dyspnea, insomnia, appetite loss, constipation, diarrhea), plus financial impact and global health/QOL ratings.[23] The recall period for most items is the past week. All domains are transformed to a 0 to 100 score, with higher scores representing better function or worse symptoms. It has been widely used in both research and clinical practice applications.[9,12,14,24-26] The QLQ-C30 was included on the basis of high ratings from our previous study.[21]

The Supportive Care Needs Survey-Short Form-34 (SCNS-SF34) is a 34-item questionnaire that addresses five need domains (psychological, health systems & information, physical & daily living, patient care & support, and sexual).[27-28] Using a 1-month recall period, patients rate each item on a 5-point scale (1 = not applicable, 2 = satisfied, 3 = low need, 4 = moderate need, 5 = high need). Item responses were averaged to calculate domain scores. The SCNS-SF34 was also included on the basis of high ratings from our previous study.[21]

The Patient-Reported Outcomes Measurement Information System (PROMIS) is a series of short forms, item banks, and computer-adaptive tests (CATs) designed to assess PROs across a variety of chronic diseases, including cancer.[29] This study used the version 1 fixed-item short forms for anxiety, depression, fatigue, pain impact, physical function, and satisfaction with social roles. Scores are normed to a general population mean of 50 and standard deviation of 10, with higher scores representing better function or worse symptoms. Most questions use a 7-day recall period.

Study Procedures

At enrollment, patients completed a sociodemographic form, and clinicians provided basic clinical information. For both study phases, patients completed their assigned PRO before their oncologist/nurse practitioner visit using the PatientViewpoint Web tool. PatientViewpoint automatically scored each PRO domain for which at least one item was completed and generated graphic score reports, with domains potentially requiring attention highlighted in yellow.[30-31] The study team trained participating clinicians on the three PRO questionnaires and score report interpretation before study initiation and provided handouts for reference.

Patients enrolled during phase 1 completed the questionnaire in the waiting room using a laptop provided by the research coordinator. The questionnaire results were printed and provided to the clinician and patient for use during the visit.

Patients enrolled during phase 2 were trained on PatientViewpoint so that they could complete their questionnaires remotely. E-mails reminded patients to complete their PRO before each clinician visit. A laptop computer was provided in the clinic if patients could not or did not complete the survey before their visit. Clinicians could view the results via the PatientViewpoint Web site, have clinic staff print hard copies, or access a plain-text score report in the electronic medical record with asterisks noting potentially problematic scores. For phase 2, clinicians received additional training on the PatientViewpoint Web tool. In both study phases, patients were monitored for the duration of treatment or until study termination (whichever happened sooner).

Outcome Measures

Patients provided feedback on the questionnaire at the end-of-study visit using a 13-item Patient Feedback Form.[32] Then, in an exit interview,[26] the research coordinator asked patients whether highlighted PRO scores were discussed and addressed, as well as for comments on the questionnaire.

A four-item Clinician Feedback Form[9,33-34] elicited clinicians' feedback regarding the PRO questionnaire after each patient's end-of-study visit. At the end of the entire study, the research coordinator conducted an exit interview[24] to obtain clinicians' perspectives on the questionnaires.

Sample Size

The primary outcome was the proportion of patients who strongly agreed/agreed to the 11 rating items on the Patient Feedback Form, thus providing a measure of a favorable rating overall. In data from Basch et al,[32] 21 of 42 patients (50%) answered strongly agree/agree to all items. A sample size of 75 in each group yielded 84% power to detect a response rate of 67% in one group and 75% in the other, compared with 50% in the reference group, with a two-sided type I error rate of 5%. We simulated responses from a binomial distribution using the above response probabilities and fit a logistic regression model to the responses with indicators of study arm. An overall χ^2 test was used to determine model significance. Power was calculated as the proportion of simulations that yielded $P < .05$, and 2,500 simulations were performed.

Analyses

After describing the study sample's sociodemographics, we compared the percentage of patients who strongly agreed/agreed to all Patient Feedback Form items by study arm using Fisher's exact tests overall and in pair-wise comparisons. We did this both for patients who completed all feedback form items, and for patients who completed at least one item. This latter outcome was used for the remainder of the analyses. We then compared Patient and Clinician Feedback Form items across study arms, cancer type, and medical versus radiation oncology.

Next, we explored associations between the primary outcome and cancer type and treatment type. We also examined the association with age (continuous), race (white *v* other), education (college graduate or more *v* less than college graduate), computer access (high-speed *v* not), computer usage (regular *v* not), performance status (0 *v* higher), and extent of disease (early, locoregional, metastatic, unknown). In addition, we investigated the association between the outcome and Clinician Feedback Form items. We also examined the association between the outcome and PRO completion patterns using proportions of the following: expected questionnaires completed, missing items within completed questionnaires, highlighted PRO domains, highlighted domains that were discussed, and highlighted domains that resulted in action. For these analyses, we first conducted Fisher's exact tests and then included variables with $P < .10$ in multivariable logistic regression models with study arm as a covariate. Finally, we tested for differences in the outcome between patients in the two study phases, and whether ratings changed over time as continuing improvements in the PatientViewpoint Web tool were implemented.

Results

Study Population and PRO Completion Patterns

Twelve (92%) of 13 clinicians approached agreed to participate in the study (five medical oncologists, four radiation oncologists, three nurse practitioners). Between October 25, 2010, and December 9, 2012, 301 potentially eligible patients were approached by study staff, and 224 (74%) enrolled (Appendix Figure A1, online only). Of the 77 who did not enroll, seven were ineligible, and 70 declined participation. Of the 224 subjects who enrolled, 22 provided no data, and 21 patients did not complete the end-of-study Patient Feedback Form. Thus, 181 (81%) of 224 enrolled patients are included in the primary outcome analysis. Overall, the median age was 66 years, 78% were white, and 70% were college graduates or higher (Table 1). Clinically, 87% had performance status of 0%, and 49% had locoregional disease. Twenty-four percent were not regular computer users, and among phase 2 subjects, 16% did not have high-speed Internet access.

Participants were prompted to complete their assigned PRO before clinic visits (weekly for radiation oncology, every 2-4 weeks for medical oncology). The number of expected surveys ranged from three to 16, depending on the questionnaire completion interval and duration of treatment. The percentage of PRO questionnaires completed was high across study arms (mean: PROMIS, 91%; QLQ-C30, 88%; SCNS-SF34, 89%; median: 100% for all arms). The rate of missing items on completed PRO questionnaires was low across the study arms (PROMIS: mean 2%, median 1%; QLQ-C30: mean 2%, median 1%; SCNS-SF34: mean 1%, median 0%).

Feedback Form Results

We found significant differences by study arm in the proportion of patients who responded strongly agree/agree to all Patient Feedback Form items (Figure 1). Of the 181 patients (81%) who completed one or more Feedback Form item, 74% of participants in the QLQ-C30 study arm strongly agreed/agreed to all items, followed by patients in the PROMIS (61%) and SCNS-SF34 (52%) arms ($P = .03$). Of the 116 subjects (52%) with complete Feedback Form data, the results were similar: 82% for QLQ-C30, 62% for PROMIS, and 56% for SCNS-SF34 ($P = .05$). In pair-wise comparisons, the only statistically significant differences were between the QLQ-C30 and SCNS-SF34. There were no significant differences on the primary outcome by cancer type or treatment type.

When examining the individual Patient Feedback Form items (Table 2), significant differences were found across study arms on seven of 11 items. There were no differences by cancer type or treatment type. Clinicians completed Feedback Forms for 178 encounters, and there were no differences by study arm. Breast cancer clinicians and medical oncology providers tended to rate the intervention more favorably than prostate cancer clinicians or radiation oncology providers, respectively (Table 2).

In univariable analyses, patients of other races were more likely to strongly agree/agree to all items compared with white patients (75% *v* 59%; $P = .09$), as were patients with less than a college degree compared with college graduates or higher (75% *v* 58%; $P = .04$) and not regular computer users compared with regular computer users (76% *v* 59%; $P = .07$). Patients who rated the intervention more favorably reported discussing a higher proportion of highlighted issues (37% of highlighted issues discussed *v* 22%; $P = .09$). None of these variables remained statistically significant in multivariable models that included study arm. We found no significant associations between Clinician Feedback Form items or any other variable related to PRO completion patterns.

Finally, we found no differences between phase 1 participants versus 2 participants and no changes in average ratings over time as we improved PatientViewpoint.

Exit Interview Results

Several patient exit interview comments were relatively consistent across the three questionnaires (eg, redundant questions, questions that were not relevant, missing prostate-specific issues). However, comments regarding the SCNS-SF34 provide information on why it was rated less favorably. Multiple patients reported difficulty understanding the questions and found the response options confusing, particularly "not applicable" versus "satisfied." As part of our

Table 1. Patient Sociodemographic and Clinical Characteristics

Characteristic	Overall (N = 224)		PROMIS (n = 74)		QLQ-C30 (n = 77)		SCNS-SF34 (n = 73)	
	No.	%	No.	%	No.	%	No.	%
Age, years								
Median	66		66		67		65	
Range	27-86		27-86		29-85		32-84	
Race								
White	174	78	54	73	63	82	57	78
Black	43	19	18	24	11	14	14	19
Other/unknown	7	3	2	2	3	4	2	2
Education								
Less than college graduate	67	31	30	41	19	24	18	24
College graduate or higher	157	70	44	60	58	75	55	75
Performance status								
0	195	87	59	80	67	87	69	95
1-3	18	7	9	12	7	9	2	2
Unknown	11	5	6	8	3	4	2	3
Cancer type								
Breast	62	28	30	41	18	23	14	19
Prostate	162	72	44	59	59	77	59	81
Treatment setting								
Medical oncology	47	21	17	23	17	22	13	18
Radiation oncology	177	79	57	77	60	78	60	82
Extent of disease								
Early stage	70	31	22	30	25	32	23	32
Locoregional	109	49	34	46	34	44	41	56
Metastatic	29	13	12	16	11	14	6	8
Unknown	16	7	6	8	7	9	3	4
Computer usage								
Regular	169	75	57	77	58	75	54	74
Occasional	27	12	7	9	7	9	13	18
Rare	10	4	3	4	5	6	2	3
Never	18	8	7	9	7	9	4	5
Internet access*								
High speed	102	82	32	78	37	86	33	82
Dial-up/low speed	7	6	3	7	2	5	2	5
None	12	10	5	12	4	9	3	8
Unknown	3	2	1	2	0	0	2	5

Abbreviations: PROMIS, Patient-Reported Outcomes Measurement Information System; QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; SCNS-SF34, Supportive Care Needs Survey-Short Form.
* n = 124: asked only of patients in second part of study.

continuous quality improvement, we added clarification to the SCNS-SF34 instructions, and one patient commented that this change helped. Several patients also reported that the answers to the SCNS-SF34 questions were unlikely to change and were, therefore, not well suited for repeated administration. Finally, the SCNS-SF34 uses a 1-month recall period, but some patients were completing the questionnaire weekly. Key feedback received specific to the PROMIS measures was confusion because the response options varied such that the answer reflecting no problem was sometimes the first option and sometimes the last. For both the QLQ-C30 and PROMIS, several patients commented that a "not applicable" option would be useful.

Most clinicians expressed no clear questionnaire preference. Some clinicians preferred the QLQ-C30 because it had graphs for specific domains, and some clinicians liked that it included issues that they frequently cover during patient visits. In contrast, some clinicians thought having the score reports on issues they already ask about in taking the history was less valuable. Some clinicians reported preferring the more global picture of the surveys that produced fewer domain scores.

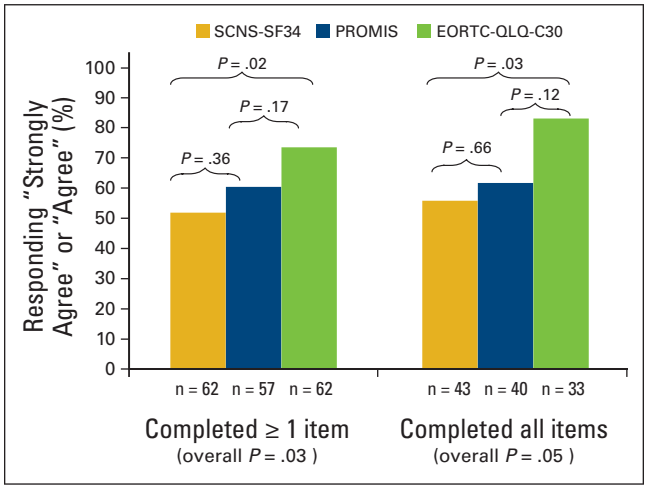

Figure 1. Proportion of patients responding "strongly agree" or "agree" on all feedback form items. EORTC-QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; PROMIS, Patient-Reported Outcomes Measurement Information System; SCNS-SF34, Supportive Care Needs Survey-Short Form.

Discussion

This RCT addressed the critical question of whether, when using PROs for individual patient management, one questionnaire is preferred over others. Our results suggest that the measure does matter to patients. The QLQ-C30 was preferred overall, with the SCNS-SF34 less preferred. Interestingly, in a previous study, patients rated the content of the SCNS-SF34 as both most important and most relevant overall, and the QLQ-C30 was preferred over the other HRQOL questionnaire.[21] In the previous study, patients saw only the item stems, not the response options, and the study design was cross-sectional.

The comments from the exit interviews identified several limitations to the application of the SCNS-SF34 in this study. Given that some of these limitations can be addressed in future studies, it is premature to conclude definitively that the measure is inappropriate for clinical practice. However, the confusion expressed by patients regarding the question wording and response options, combined with the comments that some of the content was not well suited for repeated assessment, raise concerns about its use for applications such as the one tested here.

In contrast, the findings support our previous research[21] related to the appropriateness of the QLQ-C30 for use in clinical practice. Further, because of the core-plus-module approach used by the European Organisation for Research and Treatment of Cancer,[23] the ability to supplement the QLQ-

Table 2. Patient and Clinician Feedback Form Responses by Study Arm, Cancer Type, and Treatment Setting

Feedback Form Item	Overall (N = 224)	PROMIS (n = 74)	QLQ-C30 (n = 77)	SCNS-SF34 (n = 73)	Breast (n = 62)	Prostate (n = 162)	Medical Oncology (n = 47)	Radiation Oncology (n = 177)
				% Strongly Agree/Agree				
Patient								
Questionnaire was easy to complete (n = 181)	98	**100**	**100**	**93**	100	98	100	97
Completing the questionnaire was useful (n = 178)	92	**98**	**91**	**90**	95	91	97	92
Questionnaire was easy to understand (n = 180)	95	**99**	**98**	**89**	100	93	100	94
Helped me remember when I met with doctor (n = 178)	84	**90**	**87**	**76**	90	82	88	84
Improved discussions with my doctor (n = 177)	80	84	86	71	87	78	83	80
Doctor used information for my care (n = 125)	76	73	89	68	65	79	67	77
Questionnaire improved quality of care (n = 134)	76	73	88	67	75	77	76	77
Questionnaire improved communication with doctor (n = 153)	81	76	88	77	82	80	84	80
I felt more in control of my care (n = 176)	84	**82**	**88**	**80**	88	83	83	84
Would recommend to others (n = 181)	93	**98**	**94**	**88**	95	93	97	93
Want to continue responding in future (n = 177)	85	**86**	**87**	**81**	85	85	84	85
Clinician								
Information helped promote communication (n = 138)	74	75	74	73	**94**	**67**	**88**	**71**
Information helped identify areas of need (n = 138)	67	70	72	61	**86**	**61**	**88**	**63**
Information improved quality of care (n = 137)	69	64	70	71	**85**	**63**	**84**	**65**
				% Endorsing				
Did not use for other information (n = 178)	42	36	47	42	**27**	**47**	**23**	**45**
Used for overall assessment of patient (n = 178)	47	52	38	52	49	47	**67**	**43**
Used for additional information (n = 138)	12	18	10	10	**27**	**8**	**33**	**8**
Used to confirm knowledge (n = 178)	24	29	23	21	**58**	**13**	**47**	**20**
Used to identify issues to discuss (n = 178)	16	20	17	13	**33**	**11**	30	14
Used to help with patient management (n = 178)	3	2	7	2	**13**	**0**	10	2

NOTE. Bold indicates $P < .05$ for Fisher's exact comparison of the proportion of subjects responding strongly agree/agree/disagree/strongly disagree.
Abbreviations: PROMIS, Patient-Reported Outcomes Measurement Information System; QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; SCNS-SF34, Supportive Care Needs Survey-Short Form.

C30 with cancer- and treatment-specific questions could address the desire for prostate cancer–specific issues, for example. Indeed, the importance of having tailored, relevant questionnaires for use in clinical practice has been documented.[22,35]

The need for tailored questionnaires may also support the use of PROMIS. Although this study used the fixed-item short-forms, PROMIS includes CATs for many domains.[29] CATs use the information from subjects' responses to determine questions that are applicable for their level of function, thus increasing the relevance of the questions asked.[36] However, there were some comments that the PROMIS questions were too general and broad. Although PROMIS is designed to be applicable across disease areas, some cancer-specific development work is underway,[29] and on the basis of our findings, would be important to incorporate in clinical practice applications. Although not rated the most preferred PRO overall, there was no significant difference in the ratings between the QLQ-C30 and PROMIS in this study.

Finally, an unexpected finding was that participants from minority racial groups, lower education, and less computer usage were more likely to rate the intervention favorably. This suggests that using PROs in clinical practice may be an effective approach for addressing the needs of these vulnerable populations. This study was not powered to address this question, but further research should investigate this finding.

It is important to interpret these findings in the context of the study's strengths and limitations. It used a rigorous RCT design, with a large sample size, and a priori power calculation. We obtained both close-ended questions and open-ended feedback from both patients and clinicians. Future research could record the actual interactions for direct analysis of how the PRO data were used in the clinic visit and conduct in-depth interviews to enable detailed qualitative analysis of the factors underlying differing ratings of the PRO intervention. There were some missing data, with Patient and Clinician Feedback Forms available for 181 and 178 of the 224 patients, respectively. However, there was no evidence of differential drop-out across the study arms. There were also some missing items within forms, but for our primary analysis, the results were consistent between patients who completed all items and patients who completed one or more items, indicating that there was unlikely to be bias across study arms. Although the study was not blinded and the randomization sequence was not concealed, the arms were different PROs and were considered low risk for bias. In future research, it would also be informative to have the same patient complete multiple PRO instruments randomly assigned from a pool to investigate how different instruments perform in the same patient. Finally, the study included two cancer types and both medical and radiation oncology, and future research should explore the generalizability of the findings outside of an academic cancer center and with other cancer types. Because these results suggest that the PRO measure matters, we advise careful selection of the PRO measure best suited for the particular clinical practice application.

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Authors' Disclosures of Potential Conflicts of Interest

The authors indicated no potential conflicts of interest.

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Appendix

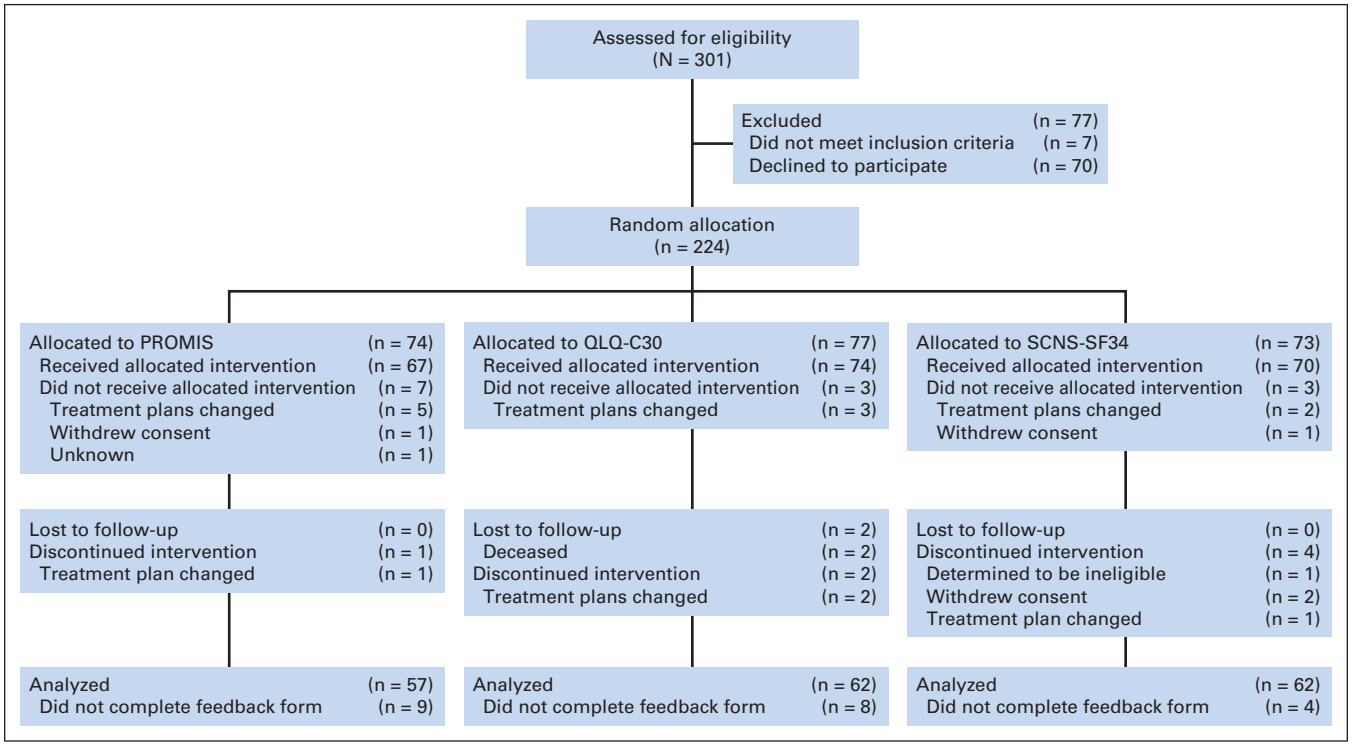

Figure A1. CONSORT flow diagram. QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; PROMIS, Patient-Reported Outcomes Measurement Information System; SCNS-SF34, Supportive Care Needs Survey-Short Form.